

**REMARKS**

**I. STATUS OF CLAIMS**

Claims 1 and 4-59 are pending in this case based on the amendments to the claims provided herein and claims 31-59 were withdrawn from consideration pursuant to a restriction requirement. Claim 1 was amended to recite the subject matter found in claims 2 and 3 and as a result, claims 2 and 3 are canceled. Support for the additional amendments to claim 1 can be found in the specification at least on pages 1-3. Accordingly, no new matter is added by this Response.

**II. REJECTION UNDER 35 U.S.C. § 112**

The Office maintained the rejection of claims 1-30 under 35 U.S.C. § 112, first paragraph as not being enabled for “disorders associated with seborrhea and disorders associated with microorganisms of the genus *Propionibacterium*.” Office Action at page 3. In response to Applicants’ argument that the specification bears a reasonable correlation to the scope of the claim (i.e., the genus is typically identifiable based on common attributes), the Office contends that “various species of the genus *Propionibacterium* do not all cause acne.” *Id.* at page 3. Specifically, the Office asserts that, for example, the species “*Propionibacterium propionicus*” is demonstrated to cause lacrimal canaliculitis (infection of the duct that carries tears from behind the eyelids to the lacrimal sac) and actinomycosis (disorder caused by *A.israelii* and *Arachnia propionila* that commonly affects the cervicofacial area, abdomen, or thorax). *Id.*

Although Applicants disagree with this rejection, in order to advance prosecution, Applicants amended claim 1 to recite the word “dermatological” to the preamble of

claim 1 and incorporated the subject matter recited in claims 2 and 3 into amended claim 1.

As provided in the specification at least one pages 1 through 3, “the present invention relates to cosmetic and pharmaceutical compositions such as, for example, *dermatological* compositions . . . .” Applicants Specification at page 1 (emphasis added). Moreover, “[a]nother subject of the invention is . . . for treating . . . the *skin* disorders associated with seborrhoea, and disorders associated with the microorganisms of the genus *Propionibacterium* . . . .” *Id.* at page 2 (emphasis added). In addition, the present specification provides for numerous examples that bear a reasonable correlation to the entire scope of the instant claims. See, e.g., Specification at pages 13-15. Thus, the specification fully supports such amendments.

Moreover, the subject matter incorporated into claim 1 from claims 2 and 3 clarify the species of *Propionibacterium* related to these dermatological disorders. Accordingly, Applicants respectfully request the withdrawal of the rejection.

### **III. REJECTION UNDER 35 U.S.C. § 102**

The Office also maintained the rejection of claims 1-10, 12-15, 25-27, and 30 under 35 U.S.C. § 102(e) over U.S. Patent No. 6,395,284 to Thunemann (“Thunemann”), as evidenced by Aldrich (1996-1997). Office Action at page 4. In Applicants’ previous response, Applicants argued that Thunemann does not teach treating acne with the polyelectrolytes, i.e., poly-L-amino acids of the composition. *Id.* In response, the Office asserts that because “comprising” is used in Applicants claims and Thunemann teaches a composition comprising a polyamino acid derivative for use in treating acne, the claims encompass the prior art composition. *Id.* In addition, “the

fact that the reference does not specifically teach the use of polyamino acids as the active agent is not persuasive because the skilled artisan would have the reasonable expectation that similar compositions would have similar properties.” *Id.* Applicants respectfully disagree for the reasons of record and for the additional reasons provided below.

Thunemann specifically identifies vitamin A as the “pharmacological active substance,” not the cationic polyelectrolytes, e.g., poly-L-amino acids. See Thunemann at Col. 1, ll. 26-40; Col. 3, ll. 3-8. Their use as “pharmacologically active substances” may include transmission of pleiotrophic effects on morphogenesis, treatment of severe acne, and/or inhibition of malignant tumors by retinoids. *Id.* at Col. 1, ll. 27-37. Thunemann further provides that “the complexation of vitamin A acid with cationic polyelectrolytes is based on the finding that the formation of ordered structures in solution or in the solid state often takes place by means of self-organization by attachment of a surface-active agent to a polyelectrolyte.” *Id.* at Col. 2, ll. 13-17. It is this complex that allows for the immobilization of vitamin A acid that is “[a] major problem in relation to the administration of Vitamin A . . . .” *Id.* at Col. 1, ll. 46-48. Thus, Thunemann’s composition at least includes Vitamin A that is known to be an active agent to treat acne and poly-L-amino acids for the complexation of vitamin A.

As provided under Section 102, “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); *see also*, M.P.E.P. § 2131. In this case,

claim 1 (from which all the other rejected claims depend) recites that "wherein the polyamino acid derivative of formula (I) and salts thereof are the *only anti-seborrhoeic agents and anti-acne active agents applied to the area in need of treatment.*" Amended Claim 1 (emphasis added). Because Vitamin A is known to treat acne and Thunemann's composition includes Vitamin A, Thuenmann's composition includes an anti-acne agent *other than* poly-L-amino acids outside the scope of the present invention and thus, fails to teach each and every element as set-forth in the claims required under Section 102. Accordingly, Applicants respectfully request the withdrawal of the rejection.

#### IV. CONCLUSION

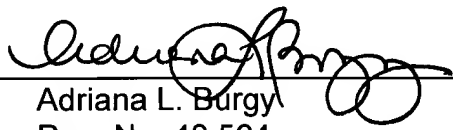
In view of the foregoing amendments and Remarks, Applicants submit that this claimed invention is allowable over the prior art references cited against this application. Applicants therefore request the Examiner's reconsideration of the application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: December 8, 2005

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